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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,111	06/28/2002	Hiroshi Yanagawa	P22033	3232

7055 7590 09/20/2005

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RESTON, VA 20191

EXAMINER

FOSTER, CHRISTINE E

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/069,111

Applicant(s)

YANAGAWA ET AL.

Examiner

Christine Foster

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's Preliminary Amendment, filed 2/27/02, is acknowledged and has been entered.

The Supplemental Preliminary Amendment filed 6/28/02 is objected to because it does not include the statement "the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing" and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b) or 1.825(d). A statement that the sequence listing information is identical is required.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-18, drawn to a method for analyzing an interaction between a protein and a molecule.

Group II, claim(s) 19-23, drawn to a labeling agent for a protein.

Group III, claim(s) 24-30, drawn to an immobilized protein and a protein chip.

Group IV, claim(s) 31, drawn to an apparatus for producing a protein chip.

Group V, claim(s) 32, drawn to an apparatus for simultaneous analyses of multiple test samples.

Group VI, claim(s) 33-37, drawn to a method for identifying a molecule which interacts with a protein or a protein that interacts with a molecule.

Group VII, claim(s) 38, drawn to a molecule having interaction with a protein.

Group VIII, claim(s) 38, drawn to a protein having interaction with a molecule.

Group IX, claim(s) 39-40, drawn to a C-terminus labeled protein.

The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-IX appears to be a C-terminus labeled protein that is capable of interacting with a target molecule, which interaction may be detected by detecting a change of a signal that is caused by the interaction.

However, Persechini (WO 98/48278, Applicant's Information Disclosure Statement filed 2/22/05) teaches a method for detecting intracellular ligand binding, wherein a protein ("primary ligand binding peptide") is labeled at the C-terminus with green fluorescent protein (p. 2, lines 13-21 in particular). The C-terminus labeled protein is capable of interacting with a target molecule ("primary ligand"), which causes a change that is detected by FRET (p. 2, lines 31-33).

Therefore, the technical feature linking the inventions of Groups I-IX does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

In addition, Groups I-IX each have technical features that are unrelated to the other groups. For example, Group I includes the step of detecting a change of a signal, which is not a feature of Groups II-IX. Group II includes the feature of a labeling agent comprising a labeling moiety and an acceptor moiety; Group III includes the feature of an immobilized protein bound to a solid phase via a labeled moiety; Group IV includes the feature of a means for holding a base plate whose surface is bound with an adapter protein; Group V includes the feature of a means for holding a chip; Group VI includes the steps of preparing a C-terminus labeled protein and judging that the protein has interacted with a target molecule; Group VII includes the feature of a molecule that interacts with a protein; and Group VIII includes the feature of a protein that interacts with a molecule.

Accordingly, Groups I-IX are not linked by the same or a corresponding special technical feature so as to form a single general inventive concept.

### *Election of Species*

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- a. In the event that Group I is elected, the following species election (for both i, ii, iii, and iv ) must also be made:
  - i. One type of target molecule (elect one of the following):

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- (1) Protein
  - (2) Nucleic acid
  - (3) Sugar chain
  - (4) Low molecular [weight] compound
- ii. One type of chemical skeleton (elect one of the following):
  - (1) Puromycin
  - (2) 3'-N-aminoacylpuromycin aminonucleoside
  - (3) 3'-N-aminoacyladenosine aminonucleoside
- iii. One combination of polypeptide and molecule (elect one of the following):
  - (1) Biotin binding protein/biotin
  - (2) Maltose binding protein/maltose
  - (3) G protein/guanine nucleotide
  - (4) Polyhistidine peptide/metal ion
  - (5) Glutathione-S-transferase/glutathione
  - (6) DNA binding protein/DNA
  - (7) Antibody/antigen molecule
  - (8) Calmodulin/calmodulin binding peptide
  - (9) Adenosine triphosphate binding protein/ATP
  - (10) Estradiol receptor protein/estradiol
- iv. One method of measuring signal change (elect one of the following):
  - (1) Surface plasmon resonance method

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- (2) Evanescent field imaging method
- (3) Fluorescence imaging analysis method
- (4) Enzyme-linked immunoabsorbent assay
- (5) Fluorescence depolarization
- (6) Fluorescence correlation spectroscopy

The claims are deemed to correspond to the species listed above in the following manner:

For (i): Claim 2

For (ii): Claim 6

For (iii): Claim 11

For (iv): Claims 12-13, 15, and 17-18

The following claim(s) are generic:

For (i): Claims 1 and 3-18 are generic. Claim 2 is subject to species election.

For (ii): Claims 1-5 and 7-18 are generic. Claim 6 is subject to species election.

For (iii): Claims 1-10 and 12-18 are generic. Claim 11 is subject to species election.

For (iv): Claims 1-11, 14, and 16 are generic. Claims 12-13, 15, and 17-18 are subject to species election.

b. In the event that Group II is elected, the following species election (for both i and ii) must also be made:

i. One type of labeling moiety molecule (elect one of the following):

- (1) Biotin

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- (2) Maltose
- (3) Guanine nucleotide
- (4) Metal ion
- (5) Glutathione
- (6) Protein binding DNA
- (7) Antigen molecule
- (8) Calmodulin binding peptide
- (9) ATP
- (10) Estradiol

ii. One acceptor moiety chemical skeleton (elect one of the following):

- (1) Puromycin
- (2) 3'-N-aminoacylpuromycin aminonucleoside
- (3) 3'-N-aminoacyladenosine aminonucleoside

The claims are deemed to correspond to the species listed above in the following manner:

For (i): Claim 22

For (ii): Claim 23

The following claim(s) are generic:

For (i): Claims 19-21 and 23 are generic. Claim 22 is subject to species election.

For (ii): Claims 19-22 are generic. Claim 23 is subject to species election.

c. In the event that Group III is elected, the following species election (for both i and ii) must also be made:



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i. One acceptor moiety chemical skeleton (elect one of the following):

(1) Puromycin

(2) 3'-N-aminoacylpuromycin aminonucleoside

(3) 3'-N-aminoacyladenosine aminonucleoside

The claims are deemed to correspond to the species listed above in the following manner:

For (i): Claim 28

For (ii): Claim 29

The following claim(s) are generic:

For (i): Claims 24-27 and 29-30 are generic. Claim 28 is subject to species election.

For (ii): Claims 24-28 and 30 are generic. Claim 29 is subject to species election.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species are different because their structures, physicochemical properties and modes of action are different, and they do not share a common structure that is disclosed to be essential for common utility. Furthermore, the examination of these species would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Foster whose telephone number is (571) 272-8786. The examiner can normally be reached on M-F 8:30-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached at (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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09/15/05